

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
	)	
Bernward SCHÖLKENS et al.	)	Prior Group Art Unit: 1614
	)	
Continuation of	)	Prior Examiner: R. Henley III
Application No.: 09/651,275	)	
	)	
Filed: Herewith	)	
	)	
For: USE OF INHIBITORS OF THE	)	
RENIN-ANGIOTENSIN SYSTEM	)	
IN THE PREVENTION OF	)	
CARDIOVASCULAR EVENTS	)	

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**Information Disclosure Statement Under 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Office the documents listed on the attached PTO form 1449. This Information Disclosure Statement is being filed together with this continuation application.

Copies of most listed documents were made of record in prior Application No. 09/651,275, filed on August 30, 2000, upon which Applicants rely for the benefits provided in 35 U.S.C. § 120. Copies of the additional following documents are enclosed:

U.S. Patent Nos. 4,587,258 and 5,196,444;

Marc A. Pfeffer, MD, PhD et al., "The continuation of the Prevention of Events With Angiotensin-Converting Enzyme Inhibition (PEACE) Trial," American Heart Journal, vol. 142(3):375-377, September 2001;

Marc A. Pfeffer, MD, PhD et al., "Prevention of Events With Angiotensin-Converting Enzyme Inhibition (The PEACE Study Design)," The American Journal of Cardiology, vol. 82(3A):25H-30H, August 6, 1998;

Berkow et al., the Merck Manual (Home Ed.) 1997, p. 93; and

Terri J. Allen et al., "Diabetic Vascular Hypertrophy and Albuminuria: Effect of Angiotensin Converting Enzyme Inhibition," Journal of Diabetes and its Complications, vol. 9:318-322 (1995).

A copy of co-pending application No. 09/645,556, filed on August 25, 2000, has been made of record. Copies of three Office Actions (papers 6, 12 and 17) in that application are enclosed.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

For the non-English language document EP 0 331 014, a Derwent Abstract has been made of record.

For the non-English language document WO 01/78747, an English language abstract appears on the cover page and a Derwent Abstract of the document has been made of record.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Office applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.


Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: October 28, 2003

By:   
Steven J. Scott  
Reg. No. 43,911

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1707-01	Appln. No.	TO BE ASSIGNED
Applicant	Bernward SCHÖLKENS et al.		
Filing Date	Filed Herewith	Group:	TO BE ASSIGNED

U.S. PATENT DOCUMENTS						
Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	4,587,258	05/1986	Gold et al.			
	5,196,444	03/1993	Naka et al.			
	5,130,333	07/1992	Pan et al.			

FOREIGN PATENT DOCUMENTS						
Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No	
WO 96/24373	08/1996	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	U.S. Application No. 09/645,556, filed on August 25, 2000
	Yusuf et al., "The HOPE (Heart Outcomes Prevention Evaluation) Study: The design of a large simple randomized trial of an angiotensin-converting enzyme inhibitor (ramipril) and vitamin E in patients at high risk of cardiovascular events," Can. J. Cardiol., vol. 12, no. 2, pp. 127-137 (1996)
	Marc A. Pfeffer, MD, PhD et al., "The continuation of the Prevention of Events With Angiotensin-Converting Enzyme Inhibition (PEACE) Trail," American Heart Journal, vol. 142(3):375-377, September 2001
	Marc A. Pfeffer, MD, PhD et al., "Prevention of Events With Angiotensin-Converting Enzyme Inhibition (The PEACE Study Design)," The American Journal of Cardiology, vol. 82(3A):25H-30H, August 6, 1998
	Berkow et al., the Merck Manual (Home Ed.) 1997, p. 93
	Terri J. Allen et al., "Diabetic Vascular Hypertrophy and Albuminuria: Effect of Angiotensin Converting Enzyme Inhibition, Journal of Diabetes and its Complications," vol. 9:318-322 (1995)
	Copy of Office Action dated June 20, 2001, in application No. 09/645,556 (Paper 6)
	Copy of Office Action dated July 29, 2002, in application No. 09/645,556 (Paper 12)
	Copy of Office Action dated April 9, 2003, in application No. 09/645,556 (Paper 17)

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1707-01	Appln. No.	TO BE ASSIGNED
Applicant	Bernward SCHÖLKENS et al.		
Filing Date	Filed Herewith	Group:	TO BE ASSIGNED

U.S. PATENT DOCUMENTS							
Examiner Initial*		Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
		H1286	02/1994	Eisman et al.			
		5,140,012	08/1992	McGovern et al.			
		5,157,025	10/1992	Aberg et al.			
		5,190,970	03/1993	Pan et al.			
		5,217,958	06/1993	Patel			
		5,298,497	03/1994	Tschollar et al			
		5,593,971	01/1997	Tschollar et al.			
		5,461,039	10/1995	Tschollar et al.			
		5,508,272	04/1996	Robl			
		5,622,985	04/1997	Olukotun et al.			
		5,952,305	09/1999	Pfeffer et al.			
		5,972,990	10/1999	Pfeffer et al.			
		5,977,160	11/1999	Pfeffer et al.			
		6,180,660	01/2001	Whitney et al.			
		5,674,893	10/1997	Behounek et al.			
		5,691,375	11/1997	Behounek et al.			
		5,202,322	04/1993	Allen et al.			
		5,219,856	06/ 1993	Olson			
		5,554,625	09/1996	Rivero et al.			
		5,827,863	10/1998	Almansa et al.			
		5,506,361	04/1996	Koh et al.			
		5,470,975	11/1995	Atwal			

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1707-01	Appln. No.	TO BE ASSIGNED
Applicant	Bernward SCHÖLKENS et al.		
Filing Date	Filed Herewith	Group:	TO BE ASSIGNED

U.S. PATENT DOCUMENTS							
Examiner Initial*		Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
		5,554,624	09/1996	Almansa et al.			

FOREIGN PATENT DOCUMENTS							
		Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
		JP10081633	03/1998	Japan			
		EP 0 457 514	11/1991	Europe			
		EP 0 459 453	12/1991	Europe			
		EP 0 461 548	12/1991	Europe			
		EP 0 508 665	10/1992	Europe			
		EP 0 738 512	10/1996	Europe			
		WO 93/20839	10/1993	PCT			
		WO 99/11260	03/1999	PCT			
		WO 00/45818	08/2000	PCT			
		WO 95/26188	05/1995	PCT			
		EP 0 482 498	04/1992	Europe			
		EP 0 079 022	05/1983	Europe			
		WO 90/05531	05/1990	PCT			
		WO 92/20673	11/1992	PCT			
		WO 94/11369	05/1994	PCT			
		WO 95/13063	05/1995	PCT			
		WO 99/09967	03/1999	PCT			
		WO 99/20260	04/1999	PCT			

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1707-01	Appln. No.	TO BE ASSIGNED
Applicant	Bernward SCHÖLKENS et al.		
Filing Date	Filed Herewith	Group:	TO BE ASSIGNED

FOREIGN PATENT DOCUMENTS							
		Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
		WO 00/18395	04/2000	PCT			
		WO 00/67737	11/2000	PCT			
		WO 01/11038	02/2001	PCT			
		WO 01/15744	03/2001	PCT			
		WO 01/76632	10/2001	PCT			
		WO 01/76573	10/2001	PCT			
		WO 01/78747	10/2001	PCT			
		EP 0 401 705	12/1990	Europe			
		EP 0 671 170	09/1995	Europe			
		EP 0 671 171	09/1995	Europe			
		EP 0 331 014	09/1989	Europe			
		WO 92/10188	06/1992	PCT			
		EP 0 474 438	03/1992	Europe			
		EP 0 426 066	05/1991	Europe			
		WO 94/07492	04/1994	PCT			
		GB 2 171 103	08/1986	Great Britain			
		EP 0 292 923	11/1988	Europe			
		EP 0 795 327	09/1997	Europe			
		WO 96/40258	12/1996	PCT			
		WO 92/19211	11/1992	PCT			
		EP 0 547 442	06/1992	Europe			

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1707-01	Appln. No.	TO BE ASSIGNED
Applicant	Bernward SCHÖLKENS et al.		
Filing Date	Filed Herewith	Group:	TO BE ASSIGNED

OTHER DOCUMENTS	
	Yusuf et al., "Effects of an Angiotensin-converting-enzyme inhibitor, Ramipril, on cardiovascular events in high-risk patients", The New England Journal of Medicine, vol. 342, no. 3, pp. 145-153 (2000)
	McKelvie et al., "Role of angiotensin converting enzyme inhibitors in patients with left ventricular dysfunction and congestive heart failure", Eur. Heart J., vol. 15, supp. B, pp. 9-13 (1994)
	Lonn et al., "Emerging approaches in preventing cardiovascular disease", British Medical Journal, vol. 318, pp. 1337-1341 (1999)
	Tsuyuki et al., "Combination neurohormonal blockade with ACE inhibitors, angiotensin II antagonists and beta-blockers in patients with congestive heart failure: Design of the Randomized Evaluation of Strategies for Left Ventricular Dysfunction (RESOLVD) Pilot Study", Can. J. Cardiol, vol. 13, no. 12, pp. 1166-1174 (1997)
	Patten et al., "Acute and long-term effects of the angiotensin-converting enzyme inhibitor, enalapril, on adrenergic activity and sensitivity during exercise in patients with left ventricular systolic dysfunction", Am. Heart J., vol. 134, pp. 37-43 (1997)
	"Diabetes and Hypertension: Experimental Models", Clin. Exp. Hypertens, vol. 21, pp. 5-6 (1999)
	Avezum et al., "Pharmacological Treatment for Myocardial Infarction Part 2: Implications of Clinical Trials of Other Adjunctive Therapies", Indian Heart J., vol. 47, pp. 95-105 (1995)
	Yusuf et al., "Anti-ischaemic effects of ACE inhibitors: review of current clinical evidence and ongoing clinical trials", Eur. Heart J., vol. 19, supp. J, pp. J36-J44 (1998)
	Gerstein et al., "Rationale and Design of a Large Study to Evaluate the Renal and Cardiovascular Effects of an ACE Inhibitor and Vitamin E in High-Risk Patients With Diabetes", Diabetes Care, vol. 19, no. 11, pp. 1225-1228 (1996)
	Avezum et al., "Recent Advances and Future Directions in Myocardial Infarction", Cardiology, vol. 84, pp. 391-407 (1994)
	Yusuf et al., "Treatment for acute myocardial infarction", Eur. Heart J., vol. 17, supp. F, pp. 16-29 (1996)
	Lonn et al., "Study Design and Baseline Characteristics of the Study to Evaluate Carotid Ultrasound Changes in Patients Treated With Ramipril and Vitamin E: SECURE", Am. J. Cardiol, vol. 78, pp. 914-919 (1996)

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce



## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1707-01	Appln. No.	TO BE ASSIGNED
Applicant	Bernward SCHÖLKENS et al.		
Filing Date	Filed Herewith	Group:	TO BE ASSIGNED

## OTHER DOCUMENTS

	Garg et al., "Overview of Randomized Trials of Angiotensin-Converting Enzyme Inhibitors on Mortality and Morbidity in Patients With Heart Failure", JAMA, vol. 273, no. 18, pp. 1450-1456 (1995)
	Martin et al., "Serum Cholesterol, Blood Pressure, and Mortality: Implications from a Cohort of 361 662 Men", The Lancet, pp. 933-936 (1986)
	Keys, "A Multivariate Analysis of Death and Coronary Heart Disease", Seven Countries, pp.1-381 Harvard University Press (1980)
	Yusuf et al., "Effect of Enalapril on Survival in Patients with Reduced Left Ventricular Ejection Fractions and Congestive Heart Failure", The New England Journal of Medicine, vol. 325, no. 5, pp. 293-302 (1991)
	Yusuf et al., "Effect of enalapril on myocardial infarction and unstable angina in patients with low ejection fractions", The Lancet, vol. 340, no. 8829, pp. 1175-1178 (1992)
	Yusuf et al., "Effect of Enalapril on Mortality and the Development of Heart Failure in Asymptomatic Patients with Reduced Left Ventricular Ejection Fractions", The New England Journal of Medicine, vol. 327, no. 10, pp. 685-691 (1992)
	Pfeffer et al., "Effect of Captopril on Mortality and Morbidity in Patients with Left Ventricular Dysfunction after Myocardial Infarction", The New England Journal of Medicine, vol. 327, no. 10, pp. 669-677 (1992)
	Serruys et al., "Does the New Angiotensin Converting Enzyme Inhibitor Cilazapril Prevent Restenosis After Percutaneous Transluminal Coronary Angioplasty", Circulation, vol. 86, no. 1, pp. 100-110 (1992)
	Abstract From the 65 <sup>th</sup> Scientific Sessions, vol. I-35, no. 207-210
	Canner et al., "Fifteen Year Mortality in Coronary Drug Project Patients: Long-Term Benefit With Niacin", JACC, vol. 8, no. 6, na. 1245-1255 (1986)
	Francis et al., "Comparison of Neuroendocrine Activation in Patients With Left Ventricular Dysfunction With and Without Congestive Heart Failure", Circulation, vol. 82, pp. 1724-1729 (1990)
	Collins et al., "Blood pressure, stroke, and coronary heart disease", The Lancet, vol. 335, pp. 827-838 (1990)
	Kannel, "Left ventricular hypertrophy as a risk factor: the Framingham experience", Journal of Hypertension, vol. 9 (suppl. 2), pp.53-59 (1991)

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1707-01	Appln. No.	TO BE ASSIGNED
Applicant	Bernward SCHÖLKENS et al.		
Filing Date	Filed Herewith	Group:	TO BE ASSIGNED

OTHER DOCUMENTS	
	Mujais et al., "Reversal of Left Ventricular Hypertrophy with Captopril: Heterogeneity of Response Among Hypertensive Patients", Clin. Cardiol., vol. 6, pp. 595-602 (1983)
	Powell et al., "Inhibitors of Angiotensin-Converting Enzyme Prevent Myointimal Proliferation After Vascular Injury", Science, vol. 245, pp. 186-188 (1989)
	Campbell-Boswell et al., "Effects of Angiotensin II and Vasopressin on Human Smooth Muscle Cells <i>in Vitro</i> ", Experimental and Molecular Pathology, vol. 35, pp. 265-276 (1981)
	Daemen et al., "Angiotensin II Induces Smooth Muscle Cell Proliferation in the Normal and Injured Rat Arterial Wall", Circulation Research, vol. 68, no. 2, pp. 450-456 (1991)
	Katz, "Angiotensin II: Hemodynamic Regulator or Growth Facotor", J. Mol Cell Cardiol, vol. 22, pp. 739-747 (1990)
	Geisterfer et al., "Angiotensin II Induces Hypertrophy, not Hyperplasia, of Cultured Rat Aortic Smooth Muscle Cells", Circulation Research, vol. 62, no. 4, pp. 749-756 (1988)
	Naftilan et al., "Induction of Platelet-derived Growth Factor A-chain and c-myc Gene Expressions by Angiotensin II in Cultured Rat Vascular Smooth Muscle Cells", J. Clin. Invest., vol. 83, pp. 1419-1424 (1989)
	Naftilan et al., "Angiotensin II Induces c-fos Expression in Smooth Muscle Via Transcriptional Control", Hypertension, vol. 13, pp. 706-711 (1989)
	Izumo et al., "Protooncogene induction and reprogramming of cardiac gene expression produced by pressure overload", Proc. Natl. Acad. Sci. USA, vol. 85, pp. 339-343 (1988)
	Dzau, "Cardiac Renin-Angiotensin System", The American Journal of Medicine, vol. 84 (suppl. 3A), pp. 22-27 (1988)
	Brunner et al., "Essential Hypertension: Renin and Aldosterone, Heart Attack and Stroke", The New England Journal of Medicine, vol. 286, no. 9, pp. 441-449 (1972)
	Meade et al., "The epidemiology of plasma renin", Clinical Science, vol. 64, pp. 273-280 (1983)
	Alderman et al., "Association of the Renin-Sodium Profile with the Risk of Myocardial Infarction in Patients with Hypertension", The New England Journal of Medicine, vol. 324, no. 16, pp. 1098-1104 (1991)
	Pfeffer et al., "Effect of Captopril on progressive ventricular dilatation after anterior myocardial infarction", The New England Journal of Medicine, vol. 319, No. 2, pp. 80-86 (1988)

Examiner	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1707-01	Appln. No.	TO BE ASSIGNED
Applicant	Bernward SCHÖLKENS et al.		
Filing Date	Filed Herewith	Group:	TO BE ASSIGNED

OTHER DOCUMENTS	
	Dunn et al., "Enalapril Improves Systemic and Renal Hemodynamics and Allows Regression of Left Ventricular Mass in Essential Hypertension", Am. J. Cardiol, vol. 53, pp. 105-108 (1984)
	Dzau, "Angiotensin converting enzyme inhibitors and the cardiovascular system", Journal of Hypertension, vol. 10 (suppl. 3), pp. S3-S10 (1992)
	Richard, "The Cellular Biology of Angiotensin: Paracrine, Autocrine and Intracrine Actions in Cardiovascular Tissues", J. Mol. Cell. Cardiol, vol. 21 (suppl. V), pp. 63-69 (1989)
	Bouthier et al., "Cardiac hypertrophy and arterial distensibility in essential hypertension", Am. Heart J., vol. 109, no. 6, pp. 1345-1352 (1985)
	Santoni et al., "Angiotensin converting enzyme inhibition, pulse wave velocity and ambulatory blood pressure measurement in essential hypertension", Clin. And Exper.-Theory and Practice, vol. A11 (suppl. 2), pp. 535-544 (1989)
	JACC, vol. 19, no. 3, abstracts 207A, nos. 768-3, 768-4, 768-5, and 768-6 (1992)
	Mak et al., "Protective effects of sulfhydryl-containing angiotensin converting enzyme inhibitors against free radical injury in endothelial cells", Biochemical Pharmacology, vol. 40, no. 9, pp. 2169-2175 (1990)
	Chobanian, "The Effects of ACE Inhibitors and Other Antohypertensive Drugs on Cardiovascular Risk Factors and Atherogenesis", Clin. Cardio., vol. 13, pp. VII-43-48 (1990)
	Chobanian et al., "Antiatherogenic Effect of Captopril in the Watanabe Heritable Hyperlipidemic Rabbit", Hypertension, vol. 15, pp. 327-331 (1990)
	Aberg et al., "Effects of Captopril on Atherosclerosis in Cynomolgus Monkeys", Journal of Cardiovascular Pharmacology, vol. 15 (suppl. 5), pp. S65-S72 (1990)
	IP et al., "Syndromes of Accelerated Atherosclerosis: Role of Vascular Injury And Smooth Muscle Cell Proliferation", JACC, vol. 15, no. 7, pp. 1667-1687 (1990)
	Ross, "The Pathogenesis of Atherosclerosis – and update", The New England Journal of Medicine, vol. 314, no. 8, pp. 488-499 (1986)
	MacMahon et al., "Blood pressure, stroke, and coronary heart disease", The Lancet, vol. 335, pp. 765-774 (1990)
	Yusuf et al., "Primary and secondary prevention of myocardial infarction and strokes: and update of randomly allocated, controlled trials", Journal of hypertension, vol. 11 (suppl. 4), pp. S61-S73 (1993)

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

## INFORMATION DISCLOSURE CITATION

Atty. Docket No. 02481.1707-01	Appln. No. TO BE ASSIGNED
Applicant Bernward SCHÖLKENS et al.	
Filing Date Filed Herewith	Group: TO BE ASSIGNED

OTHER DOCUMENTS	
	Schreiner et al., "Antihypertensive Efficacy, Tolerance, and Safety of Long-Term Treatment with Ramipril in Patients with Mild-to-Moderate Essential Hypertension", Journal of Cardiovascular Pharmacology, vol. 18 (suppl. 2), pp. S137-S140 (1991)
	Cambien et al., "Deletion polymorphism in the gene for angiotensin-converting enzyme is a potent risk factor for myocardial infarction", Letters to Nature, vol. 359, pp. 641-644 (1992)
	Yusuf et al., "Randomised trial of intravenous atenolol among 16 027 cases of suspected acute myocardial infarction : ISIS-1", The Lancet, pp. 57-66 (1986)
	Yusuf et al., "Randomised trial of intravenous streptokinase, oral aspirin, both, or neither among 17 187 cases of suspected acute myocardial infarction: ISIS-2", The Lancet, pp. 349-360 (1988)
	Cairns et al., "ISIS-3: a randomised comparison of streptokinase vs tissue plasminogen activator vs anistreplase and of aspirin plus heparin vs aspirin alone among 41 299 cases of suspected acute myocardial infarction", The Lancet, vol. 339, no. 8796, pp. 753-770 (1992)
	Goldman et al., "Saphenous Vein Graft Patency 1 Year After Coronary Artery Bypass Surgery and Effects of Antiplatelet Therapy", Circulation, vol. 80, pp. 1190-1197 (1989)
	Holmes et al., "Long-term Outcome of Patients With Depressed Left Ventricular Function Undergoing Percutaneous Transluminal Coronary Angioplasty", Circulation, vol. 87, no. 1, pp. 21-29 (1993)
	"Aspirin Effects on Mortality and Morbidity in Patients With Diabetes Mellitus", JAMA, vol. 268, no. 10, pp. 1292-1300 (1992)
	Stamler et al., "Diabetes, Other Risk Factors, and 12-Yr Cardiovascular Mortality for Men Screened in the Multiple Risk Factor Intervention Trial", Diabetes Care, vol. 16, no. 2, pp. 434-444 (1993)
	Uusitupa et al., "5-Year Incidence of Atherosclerotic Vascular Disease in Relation to General Risk Factors, Insulin Level, and Abnormalities in Lipoprotein Composition in Non-Insulin-Dependent Diabetic and Nondiabetic Subjects", Circulation, vol. 82, pp. 27-36 (1990)
	Schwartz et al., "Pathogenesis of the Atherosclerotic Lesion", Diabetes Care, vol. 15, no. 9, pp. 1156-1167 (1992)
	Donahue et al., "Diabetes Mellitus and Macrovascular Complications", Diabetes Care, vol. 15, no. 9, pp. 1141-1155 (1992)
	Deckert et al., "Microalbuminuria", Diabetes Care, vol. 15, no. 9, pp. 1181-1191 (1992)

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1707-01	Appln. No.	TO BE ASSIGNED
Applicant	Bernward SCHÖLKENS et al.		
Filing Date	Filed Herewith	Group:	TO BE ASSIGNED

OTHER DOCUMENTS	
	Mathiesen et al., "Efficacy of captopril in postponing nephropathy in normotensive insulin dependent diabetic patients with microalbuminuria", BMJ, vol. 303, pp. 81-87 (1991)
	Sampson et al., "Regression of Left Ventricular Hypertrophy with 1 Year of Antihypertensive Treatment in Type 1 Diabetic Patients with Early Nephropathy" Diabetic Medicine, vol. 8, pp. 106-110 (1991)
	Watson et al., "Effects of captopril on glucose tolerance in elderly patients with congestive cardiac failure", vol. 12, no. 6, pp. 374-378 (1991)
	Neil et al., "A Prospective Population-Based Study of Microalbuminuria as a Predictor of Mortality in NIDDM", Diabetes Care, vol. 16, no. 7, pp. 996-1003 (1993)
	Viberti et al., "Diabetec Nephropathy", Diabetes Care, vol. 15, no. 9, pp. 1216-1225 (1992)
	Stein et al., "Drug Treatment of Hypertension in Patients With Diabetes Mellitus", Diabetes Care, vol. 14, no. 6, pp. 425-448 (1991)
	Ravid et al., "Long-Term Stabilizing Effect of Angiotensin-converting Enzyme Inhibition on Plasma Creatinine and on Proteinuria in Normotensive Type II Diabetic Patients", Annals of Internal Medicine, vol. 118, no. 8, pp. 577-581 (1993)
	Weidmann et al., "Antihypertensive therapy in diabetic patients", Journal of Human Hypertension, vol. 6 (suppl. 2), pp. S23-S36 (1992)
	Kasike et al., "Effect of Antihypertensive Therapy on the Kidney in Patients with Diabetes: A Meta-Regression Analysis", Annals of Internal Medicine, vol. 118, pp. 129-138 (1993)
	Valentino et al., "A Perspective on Converting Enzyme Inhibitors and Calcium Channel Antagonists in Diabetic Renal Disease", Arch Intern Med., vol. 151, pp. 2367-2372 (1991)
	Steinberg et al., "Modifications of Low-Density Lipoprotein That Increase Its Atherogenicity", The New England Journal of Medicine, vol. 320, no. 14, pp. 915-924 (1989)
	Lonn et al., "Emerging Role of Angiotensin-Converting Enzyme Inhibitors in Cardiac and Vascular Protection", Circulation, vol. 90, no. 4, pp. 2056-2069 (1994)
	Yusuf et al., "Effect of enalapril on myocardial infarction and unstable angina in patients with low ejection fractions", The Lancet, vol. 340, no. 8829, pp. 1173-1178 (1992)
	Lewis et al., "The effect of angiotensin-converting-enzyme inhibition on diabetic nephropathy", The New England Journal of Medicine, vol. 329, no. 20, pp. 1456-1462 (1993)

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1707-01	Appln. No.	TO BE ASSIGNED
Applicant	Bernward SCHÖLKENS et al.		
Filing Date	Filed Herewith	Group:	TO BE ASSIGNED

OTHER DOCUMENTS	
	Gottlieb et al., "Effect of ramipril on mortality and morbidity of survivors of acute myocardial infarction with clinical evidence of heart failure", The Lancet, vol. 342, pp. 821-828 (1993)
	Yusuf et al., "Beta Blockade During and After Myocardial Infarction: An Overview of the Randomized Trials", Progress in Cardiovascular Diseases, vol. XXVII, No. 5 (March/April), pp. 335-371 (1985)
	"Collaborative overview of randomised trials of antiplatelet therapy— I: Prevention of death, myocardial infarction, and stroke by prolonged antiplatelet therapy in various categories of patients", BMJ, vol. 308 pp. 81-106 (1994)
	Yusuf et al., "Lipids and cardiovascular disease", Evidence Based Cardiology, BMJ Books, pp. 191-206 (1998)
	Hansson et al., "Effects of intensive blood-pressure lowering and low-dose aspirin in patients with hypertension: principal results of the Hypertension Optimal Treatment (HOT) randomised trial", The Lancet, vol. 351, pp. 1755-1762 (1998)
	Clarke et al., "Underestimation of Risk Associations Due to Regression Dilution in Long-term Follow-up of Prospective Studies", Am. Journal of Epidemiology, vol. 150, no. 4, pp. 341-353 (1999)
	Schieffer et al., "Expression of Angiotensin II and Interleukin 6 in Human Coronary Atherosclerotic Plaques", Circulation, vol. 101, pp. 1372-1378 (2000)
	Hansson et al., "Effect of angiotensin-converting-enzyme inhibition compared with conventional therapy on cardiovascular morbidity and mortality in hypertension: the Captopril Prevention Project (CAPPP) randomised trial", The Lancet, vol. 353, pp. 611-616 (1999)
	Ruggenenti et al., "Renoprotective properties of ACE-inhibition in non-diabetic nephropathies with non-nephrotic proteinuria", The Lancet, vol. 354, pp. 359-364 (1999)
	Nicoletti et al., "Cardiac fibrosis and inflammation: interaction with hemodynamic and hormonal factors", Cardiovascular Research, vol. 41, pp. 532-543 (1999)
	Sasayama et al., "New insights into the pathophysiological role for cytokines in heart failure", Cardiovascular Research, vol. 42, pp. 557-564 (1999)
	Swynghedauw, "Molecular Mechanism of Myocardial Remodeling", Physiological Reviews, vol. 79, no. 1, pp. 215-262 (1999)
	Mann et al., "Basic Mechanisms in Congestive Heart Failure", Chest, vol. 105, no. 3, pp. 897-904 (1994)

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce

## INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1707-01	Appln. No.	TO BE ASSIGNED
Applicant	Bernward SCHÖLKENS et al.		
Filing Date	Filed Herewith	Group:	TO BE ASSIGNED

OTHER DOCUMENTS	
	Deng et al., "Proinflammatorische Zytokine und kardiale Pumpfunktion", Z. Kardiol, vol. 6, pp. 788-802 (1997)
	Matsumori, "The use of cytokine inhibitors A new therapeutic insight into heart failure", Int. Journal of Cardiology, vol. 62 (suppl. 1), pp. S3-S12 (1997)

Examiner	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce